REMARKS/ARGUMENTS

Claims 1-4, 6, 7, 15, 18-21 and 25-28 are currently pending. Claims 29 and 30 are new.

I. Rejections Under 35 USC §112

The examiner rejected Claims 18 and 26-28 under 35 USC §112, first paragraph. First, the examiner argues that the specification has not enabled "promotion of reproductive efficiency or success, or fertility." Applicants respectfully disagree with the examiner's position that the specification has not enabled promotion of reproductive efficiency or success, or fertility (as set forth in detail in the Applicants' Response to the Office Action mailed April 18, 2005). However, in an effort to move forward the prosecution of this application, Applicants have amended Claims 18 and 28 to a method of promoting lactation, which the examiner has recognized as being enabled by the specification (Page 2 of the Office Action mailed December 16, 2005).

Second, the examiner argues that the specification has not enabled "prevention of all disease conditions associated with an abnormal or low level PUFA in the blood." The examiner asserts that the specification provides no working examples to show prevention of conditions associated with PUFA deficiencies. Applicants respectfully disagree with the examiner's assertion. Specifically, in Example 11 of the specification (beginning at page 12 of the application) Applicants have shown (in a mouse model) that administration of ARA can increase essential fatty acids in an animal with induced fatty acid deficiencies. In this example, a mouse model has been developed whereby essential fatty acids in the blood of the mouse are decreased. Thus, an early phase of fatty acid deficiency in pregnant mice was induced. The results show that mice fed with ARA lead to alleviation of PUFA deficiencies in the red blood cells of the female mice. The data resulting from this experiment is presented in Tables 6 to 8, on pages 17 to 19 of the application.

As can be seen from Table 7, there was a significant increase in essential fatty acids in red blood cells with mice fed ARA. The addition of ARA therefore alleviated the low essential fatty acid status in those animals. Applicants therefore have clearly shown that, in a mouse model, with low essential PUFA induced condition, ARA can alleviate the low fatty acid status. The teachings of the present application enable one of skill in the art in prevention or prophylaxis of diseases or conditions associated with the low level of PUFA in the blood by administering ARA the non-human mammal suffering exhibiting low levels of fatty acids in the blood.

Finally, the examiner recognizes that the specification is enabling for an edible formulation of ARA but argues that the specification "has not enabled any other route of administering ARA." Although Applicants believe that other methods of administration of ARA are fully enabled by the specification, Claims 18 and 26-28 have been amended to an oral administration of microbial ARA. This amendment is supported in the specification at page 4, line 3 – page 5, line 11, which specifically discusses the administration of ARA orally, via pharmaceutical compositions, and edible formulations, including oil formulations.

II. Rejections Under 35 USC §102

The examiner rejected Claims 27 and 28 under 35 USC §102(e) as being anticipated by US 6,200,624. The examiner argued that US '624 "discloses a nutritional supplement comprising 1-15% ARA and 0.1-5% DHA that can be administered to pregnant or lactating human and animal females."

Applicants have amended the method of Claims 27 and 28 to administration of microbial ARA. Support for this amendment can be found at least at page 3, lines 21-29 of the present application. The '624 patent is directed to the purification of arachidonic acid (AA) and docosahexaenoic (DHA) acid from egg yolks and the advantages to in lieu of the alternative purification methods in the prior art. The '624 patent also teaches their proposed advantages of the use of AA and DHA purified from egg yolks, in lieu of other sources. Egg yolks are an obvious source of ARA because they are known to contain high quantities of ARA and animals and humans naturally eat eggs and egg derived products. This advance in the art, the use of a microbial source of ARA, is not taught or suggested in the '624 patent, as recognized by the examiner by the removal of this rejection from Claim 18 after it was similarly amended to administration of microbial ARA in the Amendment dated September 19, 2005.

III. Rejections Under 35 USC §103

A. *Rejection of Claims 1-4, 6, 7, 15, 18-21, and 25-28 over US 6,200,624 in view of WO 98/16119*

The examiner rejected Claims 1-4, 6, 7, 15, 18-21 and 25-28 under 35 USC §103(a) as being unpatentable over US 6,200,624 (US '624) in view of WO 98/16119 (WO '119). The examiner relies upon US '624 as disclosing a nutritional supplement comprising 1-15% ARA and 0.1-5% DHA that can be administered to

pregnant or lactating human and animal females. The examiner relies upon WO '119 as teaching "an edible formulation comprising ARA used as foods for pregnant and lactating mothers." Applicants' respectfully disagree as the combination of US '624 and WO '119 does not render obvious the full scope of the claimed invention.

The examiner argues that US '624 "does not teach clearly the promotion of lactation, but this limitation is implied by the teaching of administering the dietary supplement for lactating human or animal." As Applicants have previously noted, it is unlikely that one of relative skill in the art would take the single statement of "could be used by pregnant and/or lactating females" ('624 Patent, Col. 17, lines 35-37)) to "implicitly" arrive at the present invention. Additionally, one of ordinary skill in the art would neither be motivated by any language within US '624 to combine this teaching with the teaching of WO '119 in order to arrive at the present invention, nor would the combination provide one of ordinary skill with the full scope of the claimed invention. As set forth in detail below in IIIB, contrary to the examiner's assertion, WO '119 does not teach the use of ARA to promote lactation in non-human mammals.

Furthermore, there is nothing in US '624 which would motivate one of ordinary skill in the art to substitute the egg yolk-derived PUFA with that of a different source. US '624 clearly advocates only egg yolk sources, and does not suggest that they can be replaced, or indeed are equivalent, to ARA from other sources. Indeed, if anything, US '624 teaches away from such a substitution as there were other sources of ARA, such as plants and fish, as of the filing date of the application issuing as US '624. Furthermore, unlike the present application, US '624 teaches the use of of lipids from a source that is naturally consumed by animals. In contrast, animals do not usually ingest fungal cells of the genus Mortierella. The obvious thing to do, as evidenced by US '624, is to use the ARA from a naturally occurring source such as eggs. To use microbial ARA instead, as in the present application, requires a significant step away from the teachings of the prior art and pursuance of a significantly different direction from that advocated by the art.

B. *Rejection of Claims 1, 2, 6, 7, 15, and 18 over WO 98/16119*

The examiner rejected Claims 1, 2, 6, 7, 15, 18 under 35 U.S.C. §103(a) as being unpatentable over WO 98/16119 ('119). The '119 patent does not render obvious to one of ordinary skill in the art the full scope of the present claims. The examiner's reliance upon an implication in the teaching of the '119 reference is unfounded by the reference itself. In fact, the references within WO '119 to "pregnant women" and "nursing mothers" are more likely to be used with respect to humans

than to non-humans. Additionally, when viewed in context with the rest of the sentence,

> "[t]he foods include modified milks for premature infants, modified milks for infants, foods for infants, and foods for pregnant women and nursing mothers containing the above-mentioned edible fats"
>
> one cannot find any reference to mammals, other than human.

Additionally, Applicants disagree with the examiner's assertion that "WO '119 teaches an edible formulation comprising ARA used as foods for pregnant and lactating mothers." The abstract of WO '119 makes a single statement that "[t]he foods ... for pregnant woman and nursing mothers containing [edible fats containing arachidonic acid obtained from *Mortierella*]." There is nothing in the '624 patent which teaches or suggests the use of ARA and/or DHA for the conditions claimed in the present application. WO '119 makes no mention of promotion of lactation. While '119 refers to nursing mothers, there is no specific disclosure to the promotion of lactation. Indeed, as ARA is known to naturally exist in breast milk, WO '119 seems to be teaching nothing more than supplementation of such milk by ARA. Such a teaching is entirely different from ARA promoting the lactation process in a female non-human mammal.

Furthermore, it is an unfair burden the examiner has placed upon Applicants to prove a negative, that the teachings of WO '119 are not effective in "non-human from the same mammalian species."

C. *Rejection of Claims 3, 4, 19-21 and 25 over WO '119 in view of Makrides et al.*

The examiner rejected Claims 3, 4, 19-21 and 25 under 35 U.S.C. §103(a) as being unpatentable over WO 98/16119 ('119) in view of Makrides et al. The examiner argues that "Makrides et al. teach a method to increase the DHA in breast milk by dietary supplementation of DHA in amount 0.2 – 1.3 g/day."

Applicant incorporates the arguments made in Sections II, IIIA, and IIIB above. First, Applicant argues that there is no teaching or suggestion to combine WO '119 and Makrides et al. apart from the claims of the present application. The examiner has provided no such reference within WO '119 or Makrides et al. that suggests such a combination. Additionally, even if one of skill in the art were to combine WO '119

with the teachings of Makrides et al., he or she would still not achieve the full scope of the claimed invention.

As recognized by the examiner, Makrides et al. only addresses the use of DHA. DHA is a different fatty acid than ARA. It has a different biosynthetic pathway in the body and one cannot extend the teachings concerning DHA in humans to an invention concerning ARA in animals. Therefore, in view of the deficiencies of WO '119 outlined above, even when combined, Makrides et al. and WO '119 do not teach the methods of the present invention.

In light of the arguments above, Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If the examiner still has concerns regarding allowability of the claims in this application, Applicant respectfully requests a telephonic interview with the examiner to discuss the examiner's concerns.

Respectfully submitted,

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